SF 2.6
AR 2.1

MODEM TRANSMISSION

DATE: <Date> 3/96

TO: Timothy Brincefield, USEPA, Region 10

FROM: Carl Stineman, Ecology and Environment, Inc., Buffalo

THRU: Dhroov Shivjiani, Ecology and Environment, Inc., Seattle

SUBJ: Review of Stochastic Human Health Baseline Risk Assessment
Monsanto Superfund Site
RI/FS Oversight

REF: Contract No. 68-W9-0020, Work Assignment No. 20-38-OPD4

Pursuant to your letter dated March 7, 1996, Ecology and Environment, Inc., (E & E) conducted a brief review of the above document.

The attached review focuses primarily on the four points you asked E & E to address:

Were Steve Whittaker's comments on the previous draft of the SRA addressed, and if so, was the response adequate/appropriate?

Does the assessment appear to conform to EPA guidance on Monte Carlo Analysis/ Probabilistic risk assessment (Region 3 guidance)?

Does the assessment appear to be technically sound, and if not, where and how should it be altered? and

Are the conclusions justified by the assessment?

In addition, E & E has also included our perspective on the two risk assessments.

If you have any questions, please call Carl Stineman at 716/.684-8060 or Dhroov Shivjiani at 206/624-9532.

3/96

Review of Monsanto's Stochastic Human Health Baseline Risk Assessment
Monsanto Superfund Site

1. Steve Whittaker's comments

1.1 Executive Summary

a. The language has been softened, but the new language is still not entirely accurate or appropriate. The statement that "...conservatism compounds exponentially in proportion to the number of variables in the model." is not necessarily true. It would be more accurate to say that the conservatism in the parameter estimates is compounded (much like compound interest) when the parameters are multiplied together in an exposure model. Further, it is not the use of a deterministic or stochastic model that determines the accuracy of a risk assessment; rather, it is the accuracy and representativeness of the point estimates or the parameter distributions used in the model. The statement that "point estimates may over estimate realistic risks by orders of magnitude" is vague and potentially misleading. This may be true in some cases if point estimates of RME risks are compared to the central tendency of the "true" risks, if they could be known, but it probably overstates the case if RME point estimates are compared to the 95th percentile of the true risks, roughly the value the RME estimate is intended to represent. Finally, the reference cited in support of these statements (Milloy 1995) does not appear to be a peer reviewed publication and may not be a suitable authority to cite in support of these assertions.

b. and c.
The EPA-10 BHHRA and the MW-SRA address fundamentally different future occupational scenarios. The EPA-10 BHHRA evaluates exposure that might occur if the Monsanto operations were discontinued and were replaced by some other commercial/industrial use, in which case the activity patterns of the Monsanto workers would no longer be relevant. Since the nature of an alternate C/I use of the site cannot be known at this time, the EPA-10 BHHRA used general worker exposure assumptions to evaluate this scenario. The MW-SRA argues that the entire EPA future worker scenario is unrealistic and continues to apply Monsanto worker activity pattern data to the future occupational scenario. EPA agrees that as long as Monsanto's current operations continue, future occupational risks will likely be the same or less than those estimated for current occupational exposure. EPA's future occupational scenario is intended to address the potential risks that could occur under an alternate future land use scenario. Items b and c of Steve Whittaker's previous comments are not adequately addressed in the revised MW-SRA.

d. An assessment of the risks from beryllium has been added, but the MW-SRA still does not address potential residential risks from cadmium which the EPA-10 BHHRA estimated account for 15% of the risks. The EPA Region 3 Monte Carlo Simulation guidance recommends that contaminants that account for more than 1% of risks over 1e-6 be included in the simulation. The MW-SRA also structures its residential exposure evaluation differently than the EPA-10 BHHRA estimates risks at point locations close to the facility while MW estimates risks at currently occupied residences near the site.

e. OK.

f. OK.

g. This comment does not appear to have been addressed. As discussed in item (a.) above, precision, accuracy, and reliability are not functions of the method of analysis, but rather of the accuracy and representativeness of the point estimates or frequency distributions used in the two methods. The main advantage of the stochastic method is that it provides a quantitative

3/96

method of propagating (tracking the effect of) uncertainty in the parameter values used. However, the risk estimates obtained by both methods are only as good as the initial exposure factor estimates. Bear in mind that many of the parameter distributions used in a stochastic assessment are not well known and must be estimated. When a distribution must be estimated, the maximum and minimum value and the shape of the distribution must be estimated in addition to the most likely value. The shapes selected for these distributions can have a profound effect on the frequency distribution of the risks estimated using the assumed parameter distribution, particularly the upper and lower tails of the distribution (e.g., the 95th percentile), which are of greatest interest from a risk management perspective.

1.2. Part 1. Problem Formulation

a. It is not clear whether this comment has been adequately addressed or not. The table numbers cited in the MW-SRA (Tables 5-1, 5-2, 5-4, and 5-5) are not those said to contain the ILCRs (Tables 5-3 and 5-6) in the original comment, but the values cited appear to agree with those in Table 2 of the original comments.

7

NEW COMMENTS:

Page 4, Paragraph 2
The statement that "a stochastic model provides a higher quality risk estimate." is highly subjective and depends on the definition of "higher quality" with respect to a risk estimate. Presumably, the main qualities of interest in a risk estimate are accuracy and precision. As discussed earlier, these qualities are a function of the accuracy and reliability of the parameter values or distributions used in the model, not of the type of model used. The statement is unwarranted, unsubstantiated, and prejudicial.

Page 4, Paragraph 3
This stochastic assessment does not simply extend and refine the deterministictic assessment. Rather, in several important ways it recasts the scenarios being evaluated:

> The future occupational scenario was changed from an alternate future land use scenario to a continuation of the current use;
>
> The current residential scenario was changed from evaluating exposures at point locations near the facility to exposures at currently occupied residences; and
>
> The future residential scenario was changed from assuming that future residences are uniformly distributed around the facility to placing them in the areas judged most likely to be developed.

b. This comment was not addressed. The MW-SRA continues to use a bioavailability factor to adjust the arsenic dose and toxicity to an absorbed dose basis and it adds an additional uncertainty factor to the adjustment already included in the Slope Factors by EPA to account for extrapolation from high dose, short term exposure to low dose, continuous radiation exposure. These modifications are not consistent with EPA Region 10 guidance.

1.3. PART 2. ANALYSIS:

a. This comment was not effectively addressed. The MW-SRA continues to modify the dose-rate effectiveness factor for ^{226}Ra and to apply a bioavailability factor to the intake of arsenic. The use of these factors is contrary to EPA Region 10 and Region 3 guidance as noted in the original comment.

3/96

b. This comment was not effectively addressed. Maximum entropy estimates of the distributions of uncertain parameter values are still being used in the MW-SRA contrary to EPA Region 3 guidance.

c. Exposure assumptions and distributions used in the MW-SRA:

OCCUPATIONAL EXPOSURE

1. The general approach used in the MW-SRA is structurally different from that used in the EPA-10 BHHRA. The EPA assessment looked at the risk to subpopulations of workers assumed to spend all of their time at a specific location whereas the MW-SRA assesses risks to the worker population as a whole. The EPA approach overestimates risks at high dose-rate locations for workers who do not spend their entire careers in a job that requires them to be at that location most of the time. The MW-SRA looks at the fraction of the worker population that typically would work at each location, so that if only a few workers work at a high dose-rate location that location would contribute very little to the risks of the worker population as a whole. However the risks to workers who spend most of their working time at such a location would be much higher and are not explicitly addressed by the MW-SRA. Neither approach is perfect. The current EPA approach over estimates the risks to the overall worker population to a degree for the reasons stated above, however the MW-SRA approach does not address the risks to subpopulations of workers who spend much of their time at high dose-rate locations. The latter approach is inconsistent with general EPA risk assessment guidance which specifically requires that high risk subpopulations be considered.

2. The EPA-10 BHHRA assesses risks from exposure to stockpiles of various materials using the contaminant concentrations and gamma fields associated with those materials. This approach effectively assumes that workers are in close proximity to these materials all of the time. The MW-SRA assesses risks in grid squares 1,250 feet square. Exposure point concentrations were derived for each grid square as a whole using geostatistics (kriging). This is equivalent to assuming that a worker spends an equal amount of his or her time at all points throughout the square. If a stockpile accounts for a small fraction of the area of a grid square, the contaminant concentrations and gamma field estimated for the square as a whole could be much lower than those associated with the stockpile itself. However, the stockpile may be the primary focus of a worker's job, which would require him to spend most of his time close by. It is much more likely that workers will spend the majority of their time at specific locations within a grid or grids doing a specific job than uniformly distributing their time throughout a grid.

3. DRE: EPA Region 3 guidance recommends against modifying the point estimates of RfDs and Slope Factors published in IRIS and HEAST. In addition, the distribution of the adjustment used appears to be inappropriate. The values of the dose-rate effectiveness factor (DREF), used in calculating the slope factors and described in section 2.1.3 of the report, can actually range from 1 to infinity with the most likely values falling between 2 and 10. The agency consensus judgement selected a factor of 2 which was incorporated in the Slope Factors for radionuclides published in HEAST 1995. The distribution of the additional adjustment used in the MW-SRA only allows for values of the DREF between 2 and 10, ignoring the possibility that the value could also be less than 2, falling between 1 and 2. It would appear that a more appropriate adjustment factor distribution would have limits of 0 and 2 (rather than 0.2 to 1), with a most likely value of 1.

CURRENT RESIDENTIAL EXPOSURE:

1. Structural differences between the EPA and MW risk assessments were discussed in the problem formulation section above.

2. FS: Inclusion of this factor, which accounts for the fraction of soil and dust that is soil, and has a mean value of 0.48, is questionable. Inclusion of this factor assumes that the remainder of the soil and dust ingested contains no site-related contaminants that could contribute to the total site-related exposure. Such an assumption is unsupported and unwarranted. Studies have shown that soil is a major source of house. In fact, EPA's IEUBK model, which is used for assessing childhood lead exposure, assumes that 70% of house dust is derived from soil. Airborne particles containing site-derived contaminants also could deposit indoors and contribute to site-related exposures associated with the non-soil portion of soil and dust.

3. Fl: Fraction of time spent locally (during which exposure could occur). The distribution used for this factor, a uniform distribution between 0 and 1 (0 to 100% of a resident's time) with a mean of 0.5 (50%), is simply unrealistic. This distribution assumes that 10% of the residents are at home less than 10% of their time, 25% are at home less than 25% of the time, 50% are at home less than 50% of the time, etc. This is simply unrealistic. EPA exposure assessment guidance indicates that an individual who works full time outside of the home still spends 64% of their time at home. Individuals who do not work are likely to spend considerably more time at home, especially young children, the elderly and parents caring for young children. 1990 Census data for Soda Springs shows that 38% of the population 16 years and over worked full time, 28% worked part time, and 34% did not work.

4. BFS,AS: Bioavailability factor for arsenic in soil. The MW-SRA uses a bioavailability distribution with a mean value of 0.09 (9%) based on one study that used an *in vitro* "physiologically relevant extraction procedures" to estimate the bioavailability of arsenic in soil from a single site in British Columbia. Numerous studies have shown that the bioavailability of arsenic in soil is highly dependent on the chemical form of arsenic present. The chemical form(s) of arsenic present in soil, and hence its bioavailability, is quite site-specific. Further, absorption of arsenic from soil in the gastrointestinal tract is a complex process that is not reliably simulated by "physiologically relevant extraction procedures" carried out *in vitro*. Various animal studies have reported the bioavailability of arsenic in soils to range from about 30% to 80%. Bioavailability studies carried out in miniature pigs that have a gastrointestinal tract very similar to that of humans have found the bioavailability of arsenic in soil and slag from a smelting site to be about 80% and 40% respectively. In the absence of site-specific bioavailability studies conducted in animals, or at least a detailed comparison of soils from the site with soils from a site where arsenic bioavailability studies have been conducted in animals, EPA Region 10 recommends that the bioavailability of arsenic in soil be assumed to be at least 80%.

5. EDres: Residential exposure duration (length of time residents live in the same housing unit). The MW-SRA uses a distribution with a mean of 4.6 years based on a study by Israeli and Nelson (1991). This study was considered in EPA's revised Exposure Factors Handbook but was not used as a basis for estimating ED. The 1990 U.S. Census data for Soda Springs provides the following information on the length of time householders have occupied their current housing unit:

ED	%
1 year or less	18.8
2 - 5 years	22.8
6 - 10 years	16.4
11 - 20 years	20.0

21 - 30 years	7.6
31 years or more	14.4

Assuming ED is distributed lognormally as it appears, the mean residence time is actually about 7.2 years, substantially longer than assumed in the MW-SRA. EPA risk assessment guidance recommends that the 90th percentile residence time be used as ED in the RME case. EPA's standard default estimate of the 90th percentile residence time is 30 years, however at Soda Springs it is somewhat longer than that.

FUTURE RESIDENTIAL SCENARIO:

1. The comments made regarding the factors FI and EDres under the Current Residential Scenario also apply to this scenario.

2. FO: The MW-SRA only considers outdoor exposure of future residents; it assumes that the residents receive no exposure while indoors. The rationale given in Attachment P for this is that if a residence predates the facility there will have been no opportunity for site-related ^{226}Ra to deposit in the building footprint; if a residence was constructed after the facility began operations, any site-related ^{226}Ra in the building footprint would likely have been scraped away in preparation for digging and laying the foundation. This analysis of the building footprint may be correct, however radiation is emitted omnidirectionally, not just straight up. Residents inside their homes will be exposed to gamma radiation from ^{226}Ra deposited on the soil surrounding and extending out some distance from the building. This phenomenon is known as "shine". Indoor exposure may reflect a different geometry than outdoor exposure and the structural elements of the building will provide some shielding but the exposure will not be zero as assumed in the MW-SRA. Since residents spend an average of 92% of their time indoors, according to the MW-SRA, this exposure cannot be ignored.

3. DRF: Dose reduction, or shielding, factor: This factor accounts for the shielding afforded by structures. Although this factor appears in Equation 2.2.2.2-1 on page 42, no distribution is provided in Appendix S. It appears from the discussion in Attachment P that this factor was dropped from the calculation when the authors incorrectly concluded that no site-related indoor residential gamma exposure would occur. However, when this error is corrected this factor should reappear.

   EPA assumes a shielding factor of 0.2 (20%) for residential structures. In contrast, a shielding factor of 67% is proposed in Attachment P based on the analysis of a consultant. The EPA Region 3 guidance on the use of Monte Carlo Simulations recommends against selecting parameter distributions based on professional judgement. Therefore, unless a distribution with a mean of 0.67 can be documented based on peer-reviewed sources, a value of 0.2, which represents the consensus judgement of EPA, should be used.

   The DRF has not been applied correctly in Equation 2.2.2.2-1. The DRF has been applied to the total ^{226}Ra concentration (which includes both site-related and background components) at each grid location but not to the background ^{226}Ra concentration. As a result the unshielded background concentration has been subtracted from the total (site + bkgd) shielded concentration which is incorrect. That portion of the numerator of the equation should read: $\{[([^{226}Ra]_g \times TSGF) - [^{226}Ra]_b] \times DRF\}$.

3|96

4. TSGF: Thin Shell Geometry Factor: It is not clear why a regression equation was used to define TSGF. Why not just apply the location specific TSGFs given in Table P-1 to the corresponding [226Ra]s before kriging them to get [226Ra]gs?

5. pr,g: Proportion of Residential Population Located in Particular Grids: The values of the Relative Likelihood of Development factors (RLDFs) assigned to the five Future Land Use Categories in section 2.2.2.2.6 and used to develop the pr,gs appear to be entirely arbitrary. Since the RLDFs range over 3 orders of magnitude, they have a major influence on the magnitude of the ILCRs reported and are likely to account for most of the uncertainty in the model, yet they are not even included in the sensitivity analysis in Appendix S.

1.4. Part 3. Risk Characterization

1. The questionable exposure factor values and distributions discussed in the comments on the previous section (Analysis) will affect the quantitative risk estimates discussed and the conclusions drawn in this section.

2. Based on the Pareto Plot shown in Figure 3.1.1.2-3, Heavy Equipment Operators (HEOs) appear to be a subgroup of Monsanto workers at substantially greater risk than the worker population as a whole. As noted in the MW-SRA, the HEOs account for most of the small fraction of Monsanto workers who spend most of their work days in high dose-rate grids. Therefore, they should be treated as a sensitive subgroup. The distribution of estimated ILCRs for this subgroup should be reported and discussed separately.

3. Regarding the discussion on pages 65 and 66, it should be clear from the comments provided on the analysis section that a stochastic risk assessment is just as susceptible to uncertainty in its estimates of the *distribution of risks* (arising from inappropriate choices of the mean values, ranges and shapes of the parameter distributions) as a deterministic assessment is to uncertainty in its *point estimates of risks* (resulting from some overly conservative exposure factor estimates). Bear in mind that the distribution of risks derived by the stochastic assessment is not the *true* distribution of risk at the site as the MW-SRA seems to imply, it is simply the distribution that results from all of the assumptions made about the means, ranges, and shapes of the parameter distributions used in the assessment, many of which are flawed or are simply sophisticated guesses.

   A maximum entropy solution may be a neutral assumption about the shape of a distribution but it employs no information about the actual characteristics of a factor in arriving at the assumed distribution. In other words it is a statistically elegant, but dumb process. Distributions derived in this way encompass the maximum amount of uncertainty, but bear no particular relationship to whatever the true distribution may be. Similarly, risk distributions derived using maximum entropy factor distributions may capture the maximum amount of uncertainty surrounding the underlying exposure factors, but since they involve no intelligence about the shape of the actual factor distributions there is no reason to believe that risk distributions derived from ME factor distributions are particularly accurate estimates of the *true* risk distribution.

   Precision - This term is not really relevant to a comparison between a deterministic and a stochastic risk assessment. Technically, a deterministic assessment is inherently more precise because its outcome is a single value whereas the outcome of a stochastic assessment is a distribution of values.

   Accuracy - There is no way to judge the accuracy of either type of assessment because the *true*

3/96

magnitude of the risks can never be known.

Representativeness of the risk estimates is a function of the representativeness of the exposure factor estimates used, not of the type of assessment performed. Use of a stochastic approach cannot compensate for a poor choice of exposure factor distributions.

Comparability - One reason often cited for the use of a standard set of exposure assumptions is that it provides a consistent basis for comparing risks.

Completeness - A stochastic assessment is clearly superior in this regard. However most consumers of risk estimates are only interested in two points on the continuum, the central tendency and reasonable maximum risks. A carefully executed deterministic assessment can often provide estimates of these values that are just as good as those provided by a stochastic assessment at considerably less cost. Remember that the 95th percentile risk estimated in most stochastic risk assessments, including this one, is a single point estimate of the true 95th percentile risk drawn from the underlying distribution of possible 95th percentile values that could have resulted if different assumptions had been made about the distributions of the underlying exposure factors values.

2. **Does the assessment appear to conform to EPA Region 3 guidance on Monte Carlo analysis/probabilistic risk assessment?**

The MW-SRA is generally consistent with the Region 3 guidance with the following exceptions:

The MW-SRA did not address potential residential risks from cadmium which the EPA-10 BHHRA estimated account for 15% of the risks. The EPA Region 3 Monte Carlo Simulation guidance recommends that contaminants that account for more than 1% of risks over 1e-6 be included in the simulation.

The MW-SRA applied an adjustment to the slope factor for 226Ra. The Region 3 guidance recommends that only exposure variables be included in the Monte Carlo simulation. It recommends that reference doses and slope factors established by EPA (published in IRIS or HEAST) be entered into the model as single numbers (without modifications or adjustments).

The MW-SRA used beta distributions derived using maximum entropy solutions for a number of factors with unknown distributions based on professional judgement. The Region 3 guidance recommends that when, as a last resort, professional judgement must be used to determine a parameter distribution, only triangular and uniform distributions be used.

The MW-SRA used a residential exposure duration (EDres) distribution based on generic information obtained from the literature rather than site-specific information based on Census data.

The MW-SRA used a Relative Likelihood of Development factors, that were either arbitrary or were based on professional judgement, in compiling the overall risk distribution for future residents. However, an exponential distribution was used rather than a triangular or uniform distribution as recommended in Region 3 guidance. In addition, no distribution was shown for this factor and it was not included in the sensitivity analysis.

3. **Does the assessment appear to be technically sound, and if not, where and how should it be altered?**

Overall, the MW-SRA was well done, however the distributions used for several parameters were questionable and there were a few technical errors, discussed in detail in Section 1.2 (Analysis), that reduce the technical reliability of the assessment.

4. **Are the conclusions justified by the assessment?**

The questionable exposure factor distributions discussed in the comments on Section 1.2 (Analysis) affect the quantitative risk estimates obtained and the conclusions based thereon.

5. **Perspective on the Two Risk Assessments**

Because of the many differences between the two assessments, perhaps the best way to put the two assessments in perspective is to compare their evaluations of the worst case future residential risks in grid 74 at the north end of the site. The EPA-10 BHHRA estimates future residential risks from gamma exposure to be 2e-3 in grid 74, assuming reasonable maximum exposure conditions. The MW-SRA estimates the 95th percentile risks at the same location to be 5.5e-6, about 360 times lower. Most of this difference, a combined factor of about 45, is due to differences between the mean exposure factor values used in the MW-SRA for factors that were questioned in this review (UFdre, EDres, Fl, and FO) and mean values this reviewer considers reasonable (not necessarily the EPA default values). This leaves a factor of about 8 (45 x 8 = 360) which is due to legitimate adjustments made in the MW-SRA, like the inclusion of the Thin Shell Geometry Factor (TSGF), which accounts for a factor of about 3, differences between EPA default values and mean values this reviewer considers reasonable, and uncertainty in estimates of the magnitude of all the differences discussed.

It is probably fair to say that the truth lies somewhere between the risk estimates derived in the two assessments. One (admittedly uncertain) point estimate of "the truth" can be obtained by increasing the 95th percentile estimate of the MW-SRA by a factor of 45, or decreasing the standard default EPA estimate in the EPA-10 BHHRA by a factor of 8, which gives an estimated worst case future residential ILCR in grid 74 of 2.5e-4. This estimate of "the truth" falls just above the range of risks generally considered acceptable by EPA.